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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,765	10/29/2001	Darrel Drinan	05693.0002.NPUS01	5762

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EXAMINER

MCCROSKY, DAVID J

ART UNIT	PAPER NUMBER
3736	14

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,765

Applicant(s)

DRINAN ET AL.

Examiner

David J. McCrosky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The indicated allowability of claims 57-64 is withdrawn in view of the newly discovered reference(s) to Ash et al, Kantrowitz et al and Braig et al. Rejections based on the newly cited reference(s) follow.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 164. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 188. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: On page 25, line 11 of the specification, sensor mounting head and sensor assembly are described as the same element by "head/sensor assembly 182". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 74 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braig et al in view of Ash et al. Braig et al teach a monitoring system having a control and communication module (16) that is linked to a glucose sensor and processes and encrypts a signal. See col. 5, ll. 6-9 and ll. 22-27. At least one data collection unit (24) receives data from the control and communications module (16). A remote database management system (28) receives data from the at least one data collection unit (24). See col. 4, ll. 4-7 and ll. 15-18. While disclosing use of the system with an invasive glucose sensor (col. 7), Braig et al do not teach the particulars of the sensor. Ash et al teach a biointerface head (10) comprising a mounting ring (29), which anchors the system to a dermal layer. See col. 4, ll. 5-13. A flexible transdermal conduit (14) is attached to the mounting ring (29). The sensor assembly includes the sensor (31) and transmission line (32). A sensor mounting head (15) is attached to the second end of the transdermal conduit (14). See col. 2, ll. 22-30 and ll. 36-40. Numerous biofluid access ports are provided within the sensor mounting head (15). The ports allow biofluid flow and prevent pathogens. See col. 7, ll. 1-10. Ash et al further teach a chamber within sensor mounting head (15) for delivering a therapeutic agent. See col. 2, ll. 44-46. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Braig et al with the biointerface head of Ash et al, since Braig et al teach an invasive sensor as part of the system and Ash et al disclose one such invasive sensor.

Claims 75-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braig et al in view of Ash et al as applied to claim 74 above, and further in view of Kantrowitz et al. Braig et al and Ash et al teach a monitoring system as recited for claim 74. The combination does not teach a hydrogel adhesive. However, Kantrowitz et al demonstrate that it is well known in the art to provide a coating to encourage the bonding of dermal cells to the device. See abstract. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Braig et al and Ash et al with a hydrogel adhesive, as taught by Kantrowitz et al, to encourage the bonding of dermal cells to the device.

Response to Arguments

Applicant's arguments with respect to claims 1-73 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. McCrosky whose telephone number is 703-305-1331. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJM



ERIC F. WINAKUR
PRIMARY EXAMINER